

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1654  
Examiner : Gudibande, Satyanarayan R.  
Applicant(s) : Nancy Jean Britten  
Serial Number : 10/687,986  
Filed : October 17, 2003  
Confirmation No. : 1367  
Docket No. : PC27098  
For : DISPERSIBLE PHARMACEUTICAL COMPOSITIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**APPLICATION FOR PATENT TERM ADJUSTMENT INCLUDING  
REQUEST FOR RECONSIDERATION UNDER 37 CFR § 1.705(b)**

Dear Sir:

This is a request for reconsideration of the patent term adjustment (hereinafter "PTA") which, according to the "Determination of Patent Term Adjustment Under 35 U.S.C. 1.54(b)" mailed on April 14, 2010, is 731 days. Applicants believe the PTA should be 1327 days.

1. In compliance with 37 CFR § 1.705(b), Applicants submit herewith the following:
  - (a) The fee set forth in 37 CFR § 1.18(e); and
  - (b) A statement of facts involved specifying:
    - (i) The correct patent term adjustment and the basis or bases under § 1.702 for that adjustment;
    - (ii) The relevant dates as specified in §§1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in §1.703(f) to which the patent is entitled;
    - (iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and

(iv) (A) Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such applications as set forth in § 1.704; or

(iv) (B) That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

2. In accordance with 37 CFR § 1.705, Applicants hereby authorize the payment of the fees set forth in 37 CFR § 1.705(b)(1). Please charge the fee set forth in 37 CFR § 1.18(e) and any necessary additional fees to our Deposit Account No. 16-1445.

3. A separate statement of the facts in compliance with 37 CFR § 1.705(b)(2) is attached and submitted with this application for PTA and request for reconsideration under 37 CFR § 1.705(b).

Respectfully submitted,

Dated: July 12, 2010

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**STATEMENT UNDER 37 CFR § 1.705(b)(2)**

1. This statement is respectfully submitted in support of the “Application for Patent Term Adjustment Including Request for Reconsideration under 37 CFR § 1.705(b)” for the above-referenced patent application. In view of the following, it is respectfully requested that Applicants be granted a PTA of 1327 days, if the issue fee is paid within 3 months after the date on which the Notice of Allowance is mailed.

2. The PTA according to the “Determination of Patent Term Adjustment under 35 U.S.C. § 1.54(b)” mailed on April 14, 2010, is 731 days. This determination is in error for the reasons discussed below. The factual bases for the 1327 days are set forth as follows:

(i) **“14 Month Delay” Pursuant to § 1.703(a)(1)**

In accordance § 1.703(a)(1), Applicant is entitled to a period of patent term adjustment due to the failure by the USPTO to mail an action under 35 U.S.C. § 132 no later than 14 months after the actual filing date. Applicant is entitled to a period of adjustment (credits) beginning on the day after the date that is 14 months after the date on which the above referenced application was filed and ending on the date of mailing of an action under 35 U.S.C. § 132. As shown on

PAIR, the instant application was filed October 17, 2003. The USPTO failed to mail the first action under 35 U.S.C. § 132 until February 7, 2006, 417 days after 14 months rule. Accordingly, Applicant is entitled 417 days of PTA credit, which is in agreement with the period calculated by the USPTO.

(ii) **"4 Months" PTO Response to Applicant Reply § 1.704(b)**

PTO must respond to a reply under 35 USC 132 not later than 4 months after the date on which the reply was filed. The period of adjustment (credits) begins on the day after the date that is 4 months after the date a reply under 37 CFR 1.111 was filed and ending on the mailing date of an action under 35 USC 132. As show on PAIR, Applicant's reply to a Restriction Requirement was filed August 17, 2006. The USPTO did not respond until February 7, 2008, 417 days after 4 months rule. Applicants' application was deemed to be abandoned starting from March 10, 2006, and ending on December 17, 2006. Therefore, the 4-months rule should be applied from the day of the revival of the application (which is December 17, 2006). The 4-month date after December 17, 2006, is April 17, 2007. The PTO did not issue a response until February 7, 2008, giving Applicants a PTA credit of 297 days under this 4-months rule. Accordingly, Applicant is entitled to 297 days of PTA credit, instead of the PTO giving Applicants 417 days.

(iii) **"3 Months" Applicant Delay to Respond to a Notice or an Office Action § 1.704(b)**

Applicant's PTA credits shall be reduced for the period in excess of 3 months taken to reply to any PTO notice or action. The reduction begins on the day after the date that is 3 months after the date of mailing the Office Action and ends on the date the reply was filed. (1) As shown on PAIR, a Notice to file Missing Parts was mailed January 21, 2004. Applicants replied and filed the Missing Part on June 30, 2004, which is 70 days after the 3 month rule. Accordingly, the period of PTA shall be reduced by 70 days, which is also in agreement with the period calculated by the USPTO.

(2) As shown on PAIR, an Action was mailed February 7, 2006. Applicants replied on August 17, 2006, which is 102 days after the 3 month rule. Accordingly, the period of PTA shall be reduced by 102 days, which is not indicated at the PTA History on the USPTO website.

(3) As shown on PAIR, an Office Action was mailed September 17, 2009. Applicants replied on January 19, 2010, which is 33 days after the 3 month rule. Accordingly, the period of PTA shall be reduced by 33 days, which is also in agreement with the period calculated by the USPTO.

(iv) **Abandonment**

Applicant's PTA credits shall be reduced for the period beginning on the date of abandonment and ending on the earlier of: (i) the date of mailing of the decision reviving the application; or (ii) the date that is 4 months after the date of the grantable petition to revive the application. As shown on PAIR, the application was deemed to be abandoned on March 10, 2006. Applicant filed the Grantable Petition on August 17, 2006. The 4-month date after filing Applicant's petition is December 17, 2006. The PTO mailed The Notice of Rescinded Abandonment on December 10, 2007. Accordingly, the period of the Abandonment is from March 10, 2006, to December 17, 2006, which is 283 days, which is not indicated in the PTA History on the USPTO website.

(iv) **"Three Years Delay" Pursuant to § 1.703(b)**

Applicants respectfully submit that the USPTO did not comply with the requirement of 35 U.S.C. § 1.703(a), § 1.54(b) and § 1.702(b), which requires issuance of a patent within 3 years after the date on which the application was filed under 35 U.S.C. § 111(a). Pursuant to 37 CFR § 1.702 and § 1.703, the period of adjustment of the term of the patent is the sum of the periods calculated under paragraphs § 1.703(a)-(e), to the extent that such periods are not overlapping, less the sum of the periods calculated under § 1.704 (the period of Applicant delay).

Under the recent decision of *Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir., Jan. 7, 2010) the patent term adjustment is the sum of prosecution delays attributable to USPTO and the delay

in issuing the patent beyond the three years from the filing date, less any period of actual calendar overlap between the prosecution delays and the issuance delay.

As shown on PAIR, the instant application was filed October 17, 2003. Accordingly, Applicant is entitled to an additional period of PTA credit beginning on October 18, 2006 (the date after three years from the filing date), and ending on the date of issuance of the patent if the issue fee is paid within 3 months after the date on which the Notice of Allowance is mailed, which is 1469 days of PTA credit.

The 3-Year PTO issue requirement does not include the period consumed by continued examination of the application under 35 USC 132(b), beginning on the date on which a request for continued examination of the application was filed and ending on the date the patent was issued. Applicants filed Request for Continued Examination on July 13, 2009. Accordingly, the 3-year rule delay begins from October 18, 2006, and ends on July 13, 2009, which is 999 days.

(v) **Conclusion**

In summary, Applicants are entitled to a PTA credit of 1713 days (417 under the 14-months rule, 297 under 4-month rule and 999 under 3-years rule).

The PTA credits shall be reduced by 386 days (70 under 3-month rule, 283 abandonment, and 33 under 3-month rule). Applicants respectfully submit that the 102 days delay under the 3-month rule stated above should not be counted to reduce Applicant's PTA credits because it overlaps with the 283 days of alleged abandonment.

Accordingly, Applicants are entitled to the period of **1327 days** (1713-386) under both 37 CFR § 1.702(a) and § 1.703(b).

3. In accordance with 37 CFR § 1.705(b)(2) (iii), Applicants submit that this instant application is not subject to a terminal disclaimer.

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4. In accordance with 37 CFR § 1.705(b)(2) (iv)(A) and (B), Applicants do not believe there were any circumstances where there was a failure to engage in reasonable efforts to conclude processing or examination of this application.

In view of the foregoing, it is respectfully requested that a corrected Determination of Patent Term Adjustment be issued to reflect a patent term adjustment of 1327 days.

Respectfully submitted,

Dated: July 12, 2010

  
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